

Appendix A

AP14 Rec'd PCT/PTO 18 AUG 2006

Claim Amendments

1. (Currently amended) A pharmaceutical formulation comprising a pharmaceutical acceptable salt of glycopyrronium, a solvate ~~solvates~~ or physiologically functional derivative thereof in combination with ciclesonide, a pharmaceutically acceptable salt, solvate ~~solvates~~ or physiologically functional derivative thereof and a pharmaceutically acceptable carrier and/or one or more excipients, ~~and optionally one or more other therapeutic ingredients.~~

2. (Currently amended) ~~Formulation~~ The formulation according to claim 1, wherein the pharmaceutical acceptable salt of glycopyrronium and ciclesonide are contained in the same pharmaceutical formulation (fixed combination).

3. (Currently amended) ~~Formulation~~ The formulation according to claim 1, wherein the pharmaceutical acceptable salt of glycopyrronium and ciclesonide are

contained in different pharmaceutical formulations
(free combination).

4. (Currently amended) ~~Formulation~~ The formulation
according to claim 1, comprising a compound selected
from the group consisting of [11 β ,16 α (R)]-
-16,17-[(Cyclohexylmethylen)bis(oxy)]-11-hydroxy-21-(2-
-methyl-1-oxopropoxy)pregna-1,4-dien-3,20-dion, [11 β ,16
 α (S)]-
-16,17-[(Cyclohexylmethylen)bis(oxy)]-11-hydroxy-21-
(2-methyl-1-oxoprop-oxy)pregna-1,4-dien3,20-dion, [11 β
,16 α (R,S)]-16,17-[(Cyclohexyl-
methylen)bis(oxy)]-11-hydroxy-21-(2-methyl-1-oxoprop-
oxy)pregna-1,4-dien3,20-dion, 16 α ,17-
(22R)-Cyclohexylmethylenedioxy-11 β ,21-dihydroxy-
pregna-1,4-dien-3,20-dion, 16 α ,17-(22S)-
Cyclohexylmethylenedioxy-11 β ,21-dihydroxy-
pregna-1,4-dien-3,20-dion and 16 α ,17-
(22R,S)-Cyclohexylmethylenedioxy-11 β ,21-dihydroxy-
pregna-1,4-dien-3,20-dion.

5. (Currently amended) ~~Formulation~~ The formulation according to claim 1, wherein the pharmaceutical acceptable salt of glycopyrronium is selected from ~~[[form]]~~ the group consisting of ~~compounds~~ racemic forms [S,S-, S,R, R,S- and R,R-forms] of the pharmaceutical acceptable salt of glycopyrronium in any mixing ratio and enantiomerically enriched S,S-, S,R, R,S- and R,R-forms of the pharmaceutical acceptable salt of glycopyrronium.

6. (Currently amended) ~~Formulation~~ The formulation according to claim 5, wherein the enantiomerically enriched form of the pharmaceutical acceptable salt of glycopyrronium is the R,R-form (i.e. (3R,2'R)-3-[(cyclopentylhydroxyphenylacetyl)oxy]-1,1-dimethylpyrrolidinium).

7. (Currently amended) ~~Formulation~~ The formulation according to claim 6, wherein the R,R-form has an enantiomeric purity of 90% minimum enantiomeric excess (ee), ~~preferably 95 % ee, more preferably more than 98 % ee, and in particular preferably more than 99.5 % ee.~~

8. (Currently amended) ~~Formulation~~ The formulation according to claim 1, wherein the pharmaceutical acceptable salt of glycopyrronium is (3R,2'R)-3-[(cyclopentylhydroxyphenylacetyl)oxy]-1,1-dimethylpyrrolidinium bromide, which substantially does not contain glycopyrronium in the S,S-, S,R- and/or R,S- forms.

9. (Currently amended) ~~Formulation~~ The formulation according to claim 1, comprising pharmaceutical acceptable salt of glycopyrronium and ciclesonide in an amount and ratio to be effective for a twice or once daily treatment of a clinical condition in a mammal, ~~such as a human,~~ for which a corticosteroid and/or an anticholinergic agent is indicated.

10. (Currently amended) ~~Formulation~~ The formulation according to claim 1, which is suitable for administration by inhalation.

11. (Currently amended) ~~Formulation~~ The formulation according to claim 1, which is suitable for nasal administration.
12. (Currently amended) ~~Pharmaceutical~~ The formulation according to claim 1, which is a dry powder and the carrier is a saccharide.
13. (Currently amended) ~~Pharmaceutical~~ The formulation according to claim 12, wherein the carrier is lactose monohydrate.
14. (Currently amended) ~~Method for the prophylaxis or~~ A method of treatment of a clinical condition in a mammal, such as a human, for which a corticosteroid and/or an anticholinergic agent is indicated, which comprises administration of a therapeutically effective amount of a pharmaceutical formulation comprising ciclesonide or a pharmaceutical acceptable salt, solvate, or physiologically functional derivative thereof in combination with a pharmaceutical acceptable salt of glycopyrronium, a solvate, or physiologically functional derivative

thereof, and a pharmaceutical acceptable carrier and/or one or more excipients.

15. (Currently amended) ~~Method~~ The method according to claim 14, wherein the clinical condition is selected from the group consisting of asthma, nocturnal asthma, exercise-induced asthma, chronic obstructive pulmonary diseases (COPD), chronic bronchitis, [[and]] wheezy bronchitis, emphysema, [[,]] shortness of breath, respiratory tract infection, [[and]] upper respiratory tract disease, rhinitis, allergic rhinitis and seasonal rhinitis.

16. (Currently amended) ~~Method~~ The method according to claim 15, which comprises a twice daily dosage regimen.

17. (Currently amended) ~~Method~~ The method according to claim 15, which comprises a once daily dosage regimen.

18. (Currently amended) ~~Method~~ The method according to claim 15, which comprises administration of a combination of [[the]] a pharmaceutical acceptable

salt of glycopyrronium and ciclesonide in the same administration form by inhalation from an inhaler and wherein each actuation provides a dose therapeutically effective for a twice daily dosing regimen or for a once daily dosing regimen.

19. (Currently amended) ~~Dry~~ A dry powder inhalation product comprising a pharmaceutical composition according to claim 13.